**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF NEW JERSEY**

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| PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, and ENDO PAR INNOVATION COMPANY, LLC<br><br>*Plaintiffs*,<br><br>v.<br><br>SANDOZ INC.<br><br>*Defendant*. | Case Action No. 3:18-cv-14895-BRM-DEA<br><br>Brian R. Martinotti, U.S.D.J.<br><br>Douglas E. Arpert, U.S.M.J. |

**DEFENDANT SANDOZ INC.'S CLAIM CONSTRUCTION CLOSING ARGUMENT**

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Pursuant to the Court's request for closing arguments on claim construction (Hr'g Tr., 59:18-20), Sandoz respectfully requests that the Court adopt Sandoz's constructions for the disputed terms because they stay true to the claim language and are supported by the intrinsic evidence consistent with *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc).

## I. THE "ADMINISTERING" CLAIM TERMS.

Nothing in Par's briefs or argument at the *Markman* hearing changes the fact that the "administering" claims expressly define the properties of the formulation that must be administered to the patient. Sandoz's proposed construction requires those claimed properties, while Par's construction reads those properties out of the claims and violates multiple canons of claim construction. That is no surprise as Par's construction is engineered to eliminate Sandoz's non-infringement defense for four of the six patents-in-suit, namely the '478, '209, '526, and '223 patents. But that is an improper use of claim construction. *See Am. Piledriving Equip. v. Geoquip, Inc.*, 637 F.3d 1324, 1331 (Fed. Cir. 2011) ("It is well settled that the role of a district court in construing claims is not to redefine claim recitations or to read limitations into the claims to obviate factual questions of infringement . . . .").

### A. Judge Connolly Did Not Address Sandoz's Claim Construction.

There is a critical difference between Sandoz's proposed construction and the claim construction that Eagle proposed. Eagle asked for a construction that expressly excluded dilution. Sandoz's construction does not. Judge Connolly therefore never considered Sandoz's construction. Judge Connolly's construction is silent regarding whether the vasopressin formulations that are the subject of the "administering" limitations must have the properties recited in the claim, which is the essence of Sandoz's construction here.

Judge Connolly held that the "administering" terms have their "[p]lain and ordinary meaning" and need no construction. (Dkt. 52-1, Ex. 7.) Because the parties disagree about

whether the formulation that is administered to the patient must have the properties required in the claims, Sandoz asks the Court to define that plain and ordinary meaning and resolve the dispute between the parties. *See O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1360-63 (Fed. Cir. 2008) (reversing "ordinary meaning" construction because it did not resolve the dispute between the parties).

Par contends the Federal Circuit "confirmed" Judge Connolly's ruling in *Eli Lilly v. Hospira*, 933 F.3d 1320 (Fed. Cir. 2019). Not true. *Eli Lilly* is not a claim construction decision. The Federal Circuit simply applied the district court's claim construction to the accused product and found no literal infringement. *Id.* at 1329. Moreover, the claims in *Eli Lilly* only required the administration of pemetrexed disodium; they did not specify any properties of that pemetrexed disodium. *Id.* at 1325. In this case, Par's "administering" claims do not merely require the administration of vasopressin. They recite specific properties of the vasopressin formulation that must be administered to the patient. The Federal Circuit never held that a court may disregard those properties when construing an "administering" limitation.

**B. The Formulation That Is Administered To The Human Patient Must Have The Claimed Properties; The Formulation In The Vial Is Irrelevant.**

In its briefs and at the *Markman* hearing, Par focused on the properties of the vasopressin formulation in the vial and not what goes into the vein of a human. (Hr'g Tr., 5:6-7, 6:7-11 ("[T]hat's what you get in the vial."); Par's Markman Presentation, slides 14-15.) But the "administering" claims concern methods of "increasing blood pressure *in a human*." (Emphasis added.) The formulation that is administered "to the human" achieves this result, which is not necessarily the formulation in the vial. For this reason, the "administering" claims explicitly state that the formulation must have certain properties when administered "to the human."

Par's proposed construction of the "administering" terms concedes this point by acknowledging that the claim focuses on what is administered "into a vein of the human," not what is in a vial in the pharmacy. (Dkt. 52-1, Ex. 20, ¶ 20.) Yet Par's construction reads the properties of the formulation that is "administer[ed]" to the human out of the claim by ignoring the properties that must be present at the time the formulation reaches the vein. In doing so, Par's construction violates a cardinal rule of claim construction. *Power Mosfet Techs., L.L.C. v. Siemens AG*, 378 F.3d 1396, 1410 (Fed. Cir. 2004) ("[I]nterpretations that render some portion of the claim language superfluous are disfavored . . . .") And, for this additional reason, this Court should reject Par's construction.

**C. Par Claimed Different Embodiments In Different Patents.**

The claims of the '239 patent require administration of a "diluted unit dosage form" having one concentration of vasopressin ("0.1 units/mL to about 1 unit/mL"), while the claims of the '478, '209, '526, and '223 patents require administration of a "unit dosage form" or "pharmaceutical composition" having a different concentration of vasopressin ("about 0.01 mg/mL to about 0.07 mg/mL"). This difference in claim language teaches that the claims of the '478, '209, '526, and '223 patents cover different embodiments than the claims of the '239 patent and that the claims of the '478, '209, '526, and '223 patents should not be rewritten to cover the "diluted unit dosage form" embodiments. *See Arlington Indus., Inc. v. Bridgeport Fittings, Inc.*, 632 F.3d 1246, 1254-55 (Fed. Cir. 2011). This difference certainly does *not* suggest that the claims of the '478, '209, '526, and '223 patents should be broadened to cover the claims of the '239 patent.

This difference in claim language mimics the language used in the specifications to describe different embodiments. While Par relies on these different embodiments to support a broad construction of "administering," there is no requirement that every claim cover every

embodiment. *Pacing Techs., LLC v. Garmin Int'l, Inc.*, 778 F.3d 1021, 1026 (Fed. Cir. 2015). Instead, the fact that the '239 patent claims track one family of embodiments and the '478, '209, '526, and '223 patent claims track the second family of embodiments confirms that the two embodiments should be kept separate and should not be conflated. *See Haemonetics Corp. v. Baxter Healthcare Corp.*, 607 F.3d 776, 782 (Fed. Cir. 2010) ("[T]he description of two embodiments with each tracking the language of different independent claims most reasonably supports a construction in which 'centrifugal unit' has one meaning in claim 1 and another in claim 16."); *Otsuka Pharm. Co. v. Torrent Pharms. Ltd.*, 99 F. Supp. 3d 461, 482 (D.N.J. 2015).

**D. Claim Differentiation Does Not Save Par's Flawed Claim Construction.**

Claim differentiation does not control the construction of the "administering" claim terms because the dependent claims of the '526 patent are inconsistent with independent claim 1 regardless of how the Court construes those terms. For example, claim 1 requires administration of a formulation having 0.01 mg/mL to 0.07 mg/mL of vasopressin, whereas claim 17, which ultimately depends from claim 1, requires administration of a formulation having 0.00021 mg/mL to 0.0021 mg/mL of vasopressin.[1] Administration of a formulation containing 0.00021 mg/mL of vasopressin would be covered by claim 17, but it would not be covered by claim 1 because 0.00021 mg/mL is outside of claim 1's range of "about 0.01 mg/mL to about 0.07 mg/mL of vasopressin." Thus, even under Par's construction, claim 17 is an improper and invalid dependent claim because it covers subject matter that is not covered by claim 1. *Pfizer Inc. v. Ranbaxy Labs. Ltd.*, 457 F.3d 1284, 1292 (Fed. Cir. 2006) (dependent claim was invalid because it was broader than the independent claim). Because claim 17 is invalid regardless of

[1] Claim 17 requires "from about 0.21 µg/mL to about 2.1 µg/mL of vasopressin." 1 mg is equivalent to 1000 µg. Thus, the claimed range is 0.00021 mg/mL to 0.0021 mg/mL.

how the court construes the claims, it does not suggest that the "administering" terms should be broadened beyond their plain meaning. To the contrary, it indicates that the dependent dilution claims of the '526 patent are simply poorly written claims that have no impact on claim construction. *Regents of Univ. of Cal. v. DakoCytomation Cal., Inc.*, 517 F.3d 1364, 1375 (Fed. Cir. 2008) (declining to apply claim differentiation).

Dependent claims "are only an aid to interpretation and are not conclusive. The dependent claim tail cannot wag the independent claim dog." *N. Am. Vaccine, Inc. v. Am. Cyanamid Co.*, 7 F.3d 1571, 1577 (Fed. Cir. 1993). That is true here where dependent claim 17 is inconsistent with independent claim 1 and the "administering" claims are clear on their face. On these facts, it would be inappropriate to rely on the dependent claims to rewrite the plain meaning of the independent claims. *See Seachange Int'l, Inc. v. C-COR Inc.*, 413 F.3d 1361, 1369, 1375 (Fed. Cir. 2005) (rejecting application of claim differentiation); *Baxalta Inc. v. Genentech, Inc.*, No. 17-509-TBD, 2018 U.S. Dist. Lexis 204571, at *32 (D. Del. Dec. 3, 2018) (Dyk, J.) (same).

The fact that claim 17 is broader, not narrower, than claim 1 distinguishes those cases that have applied claim differentiation. For example, in *Cochlear Ltd. v. Oticon Med. AB*, No. 3:18-cv-6684-BRM-DEA, 2019 U.S. Dist. Lexis 142089, at *17-18 (D.N.J. Aug. 21, 2019), this court declined to adopt a narrow claim construction that sought to read in a requirement that the "circumferential groove" be "distinct from the screw thread and from the flange" because, among other reasons, that limitation was the subject of a dependent claim that narrowed the required "circumferential groove." That is not the case here. Sandoz does not seek to read a narrowing limitation from a dependent claim into an independent claim. Sandoz simply asks the

court to hold Par to the words it chose in the independent claim. It is Par that improperly seeks to read broadening language from claim 17 into claim 1.

## II. "VASOPRESSIN."

Par cannot meet the demanding lexicography or disclaimer standard required to import limitations into the ordinary meaning of "vasopressin." Par confirmed at the hearing that its proposed construction of "vasopressin" reads three limitations into the term: (i) that the vasopressin be arginine vasopressin (Hr'g Tr., 18:24-25); (ii) that it has a particular SEQ. ID No. (*id.* at 18:5-7); and (iii) that the vasopressin be synthetic, as opposed to naturally produced by the brain (*id.* at 18:19-25). Par does not identify anything in the patents' specifications that meets the high standard required for lexicography or disclaimer that could import these three limitations into the otherwise broad ordinary meaning of the term "vasopressin." *See Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1371 (Fed. Cir. 2014).

Par's request to read a "synthetic" requirement into "vasopressin" is the most tenuous of the three limitations it seeks to read into the claims. To get to "synthetic," Par asks to read into the claims one particular feature of the first sequence ID number listed in columns 25-26 of the '239 patent as a "non-limiting embodiment[]." (Dkt. 53-1, Ex. 4, 25:17-19.) The specification states "OTHER INFORMATION: Description of Artificial Sequence: Synthetic peptide." (*Id.* at cols. 25-26.) This mention of "synthetic" as just one feature of one illustrative example is a far cry from lexicography or disclaimer restricting "vasopressin" to synthetic vasopressin. *See Hill-Rom*, 755 F.3d at 1371. (*See also* Dkt. 53-1, Ex. 4, 25:17-19.) The only other reference to synthetic vasopressin in the specification states only that vasopressin "can be" synthetically made – not that it must be or always is. (Dkt. 53-1, Ex. 4, 24:15-19.) Indeed, other passages of the specification expressly state just the opposite: that "vasopressin" is made in the brain—naturally. (*Id.* at 2:8-13.)

With respect to the SEQ. ID No. limitation, Par incorrectly suggests that using a reference to the specific sequence identifier in the claim is optional under 37 C.F.R. § 1.821. (Hr'g Tr., 28:5-19.) To the contrary, the Manual of Patent Examining Procedure ("MPEP") explains that "reference ***must*** be made to the sequence by use of the sequence identifier, preceded by 'SEQ ID NO:'" even where the sequence itself is also embedded in the specification's text or claims. MPEP § 2422 (emphasis added) (citing 37 C.F.R. § 1.821(d)).

Par seeks to read limitations into "vasopressin" in order to help it distinguish prior art vasopressin formulations derived from naturally occurring vasopressin having the claimed ingredients and pH. For example, Lithuanian Patent No. 4487 ("LT 4487") discloses a formulation with the claimed excipients having a pH of 3.80-3.95 and naturally occurring arginine vasopressin. (*See* Ex. 32, LT 4487 at PAR-VASO_0233013 ("The active ingredient is arginine vasopressin; it is excreted from animal posterior lobe pituitary extract, purified by a high-performance chromatography (HPLC) . . . .").) But the intrinsic evidence does not support reading limitations into "vasopressin" that might assist Par in distinguishing the prior art.

## III. "CONSISTS ESSENTIALLY OF."

At the *Markman* hearing, the Court expressed its concerns about deciding whether "consists essentially of" is indefinite without the benefit of expert testimony. While not conceding that expert testimony is required for this analysis, in view of the Court's concerns Sandoz respectfully suggests that the Court defer ruling on this issue until after trial so that the Court can decide the issue based on a full record. *See, e.g.*, *Adapt Pharma Operations Ltd. v. Teva Pharms. USA, Inc.*, No. 16-7721, 2019 U.S. Dist. Lexis 69409, at *16-17 (D.N.J. Apr. 22, 2019); *Research Frontiers, Inc. v. E Ink Corp.*, No. 13-1231-LPS, 2016 U.S. Dist. Lexis 38441, at *68 (D. Del. Mar. 24, 2016) ("the Court believes it better to address an indefiniteness challenge at a later time with a more developed record").

## IV. "WHEREIN THE IMPURITIES ARE DETERMINED BASED ON."

Claim 11 of the '209 patent and claim 2 of the '785 patent require that the impurities "are determined"—not that they "can be" determined—using the claimed high performance liquid chromatography ("HPLC") method. Use of the claimed HPLC method to determine the impurities is the only limitation in each of these claims. As a result, converting that single limitation into an optional "can be determined" limitation would "essentially render [those claims] meaningless and violate an important axiom of claim construction." *Cochlear*, 2019 U.S. Dist. Lexis 142089, at *18-19.

Uncomfortable with the words it chose to claim its invention, Par switches gears to a widget analogy. But the widget analogy fares no better. If claims to a widget require weighing that widget using a specific method, then that method—just like the HPLC method in Par's patents—must be performed in order to infringe the claims. If Par did not want to limit the claims to a particular HPLC method, it did not have to include that method in the claims. In fact, that is exactly what Par did in claim 1 of the '785 patent and claim 1 of the '209 patent. But Par chose to include a specific HPLC method in dependent claim 11 of the '209 patent and dependent claim 2 of the '785 patent. It is bound by that language and it may not read the HPLC method out of the claims by making it optional. For this reason, the "wherein" clause of claim 11 of the '209 patent and claim 2 of the '785 patent should be construed to require determining the impurities using the claimed HPLC method. *Id*.

## V. CONCLUSION.

For the foregoing reasons, Sandoz respectfully requests that the Court adopt its constructions of the disputed claims terms.

Dated: January 31, 2020

Respectfully submitted,

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**CERTIFICATION OF SERVICE**

I hereby certify that on January 31, 2020, the foregoing document was filed via CM/ECF with the Clerk of the Court and was thereby served on all counsel of record in this matter.

Dated: January 31, 2020

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